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Stability Assessment of Cinnarizine in Self-Emulsifying Drug Delivery Systems

Ahmad A. SHAHBA, Fars K. ALANAZI, Kazi MOHSIN* & Magdi ABDEL-HAMID

Kayyali Chair for Pharmaceutical Industries, Department of Pharmaceutics, College of Pharmacy, King Saud University, P.O. Box 2457, Riyadh, 11451, Kingdom of Saudi Arabia

***SUMMARY*. The current study was designed to evaluate the chemical and physical stability of cinnarizine within self-emulsifying drug delivery systems. According to International Conference of Harmonization guidelines, the selected formulations were enrolled into both accelerated and long-term stability studies up to 6 and 12 months, respectively. The chemical stability of the formulations was assessed periodically based on the intact cinnarizine level. The physical stability was evaluated based on the physical appearance and color change pattern of the formulations. The accelerated stability study revealed significant cinnarizine degradation in all the tested formulations at 3 and 6 months. All the tested formulations experienced sharp discoloration within 6 months of storage. On the other hand, the long-term stability study showed no significant cinnarizine degradation or color change within the formulations containing 100 % saturated medium chain glycerides (as oil component). While, the formulations containing 50 % unsaturated long chain fatty acids showed considerable drug degradation as well as significant discoloration. Accordingly, The formulations containing 100 % saturated medium chain glycerides provide excellent chemical and physical stability pattern and have the potential to provide a stable dosage form of cinnarizine.**

KEY WORDS: Cinnarizine, Lipid-based formulations, Oral drug delivery, SEDDS, SNEDDS, Stability.

*Author to whom correspondence should be addressed. *E-mail:* kazimohsin@hotmail.com